IQVIA's Experience and Expertise in Radiopharmaceutical Clinical Trials

Accelerate your breakthrough treatments to waiting patients

Radiopharmaceuticals have been widely used in detecting, diagnosing, and treating cancer patients. Rapid development has occurred over the past decade and the excitement continues to drive innovation. The ability to target cancer cells with precision while minimizing damage to healthy cells brings hope to redefine cancer care.

Radioligand therapy (RLT) is a type of nuclear medicine that targets markers on tumor cells and/or their microenvironment to deliver treatment primarily to the affected tumor cells while sparing surrounding healthy cells. A radioligand is composed of two key components, a therapeutic radioisotope, and a ligand designed to recognize and attach to a surface protein of a cancer cell. RLTs have shown clinical benefit in treating neuroendocrine tumors and advanced prostate cancer. This has led to clinical research for treatment of new indications and other advanced cancers, including rare or aggressive cancers.

Radiopharmaceutical clinical trials are complex and require considerations for study planning and execution. Manufacturing locations are limited due to short half-lives. Shipment time delay can cause radioactive decay. Regulatory requirements vary across countries. Clinical trial sites need licenses to handle radioactive materials, which reduces the number of eligible sites. Patients may have more anxiety and fear about radioactive material, impacting patient recruitment. Lastly, specialty equipment and set up are needed to run trials.

IQVIA is a global leader in oncology clinical development who has worked with pharmaceutical and biotech companies in developing novel cancer drugs. In the past 5 years, IQVIA conducted more than 25 radiopharmaceutical phase I – IV studies.

25+ Studies

40 Countries

> 800 Site activations

5,000+ Patients enrolled

From this experience, we understand there is no one-size-fits-all approach. We know how important cooperation, coordination and communication is with each step along the way. We have translated our lessons learned into best practices for successful execution.

"By making intelligent connections, IQVIA brings innovation to the needs of today's development to help you anticipate and manage risks appropriately."

Best practices for successful execution of radiopharmaceutical clinical trials

Drug manufacturing and distribution logistics

- Consider **manufacturing** location, limitation in material, half-life and coordination to trigger and track IMP shipment
- **Contingency** plan for shipment challenges, country/site shutdowns

Site feasibility

- Extensive **site mapping.** Ensure that the process flow between IP, patients, assessments, and samples is well understood
- **Site training** on imaging, data entry, calibration and dosimetry

Patient recruitment and pathway

- Requirements for **patient dosing** and post-dose
- **Containment** of samples
- Understand the **recruitment pathway** at each site and harness the relationship between the nuclear medicine and oncology staff

Partner management

- **Early and frequent engagement** with partners such as imaging, dosimetry and central labs to understand study and site requirements
- Work **directly with partners** to fully align operational processes

Regulatory considerations

- **Heterogeneity** in regulatory frameworks across regions
- Specificities regarding site **radioactivity licenses** and locally required additional authorizations

IQVIA is also conducting research on the clinical use and healthcare system barriers of RLT. Through discussions and workshops with industry leaders, IQVIA has begun to identify overall capacity for RLT trials in different European countries. This research provides initial estimates to quantify site capacity and focus regions for RLT trials. Read the IQVIA Institute Report titled, Succeeding with Innovation: The State of Radioligand Therapy Readiness in Europe for more information.

The demand to treat patients with RLT is anticipated to grow. Pharmaceutical and biotech companies continue to invest into evaluating the potential of RLTs to treat rare or aggressive cancers to help improve survival rates and quality of life.

It takes an experienced partner to successfully execute radiopharmaceutical clinical trials. IQVIA is committed to making sure that all of the unique needs are streamlined within our clinical trial operations. By making intelligent connections, we bring innovation to the needs of today's development to help you anticipate and manage risks appropriately.

Connect with us about your specific radiopharmaceutical needs and we can help you navigate this challenging clinical development landscape.

Let us help you accelerate your breakthrough treatments to waiting patients.

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